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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,991	12/15/2003	Robert Alan Goodnow JR.	21366 US1	4512

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EXAMINER	
BOWMAN, AMY HUDSON	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 08/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,991	GOODNOW ET AL.	
	Examiner	Art Unit	
	Amy H. Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/9/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *2,4,6-13,15-18,20-24,26,27,29,31,32 and 34-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,14,19,25,28,30 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 December 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/15/03, 5/14/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

T.D

DETAILED ACTION

Applicant's election with traverse of group I, claims 1, 3, 5, 14, 19, 25, 28, 30 and 33, in the reply filed on 6/9/2005 is acknowledged. Applicant asserts that they do not believe a serious burden exists for the examiner to search and examine groups I-XIV together since all of these groups are classified in the same class and subclass. Further, applicant asserts that they have performed a search of class 514 and subclass 44 and do not believe that this class and subclass contain an undue number of references that would result in a burden. Applicant asserts that all of the claims are limited to "some type of G protein coupled receptor" and searching such terms should produce a limited number of references.

On the contrary, searching "some type of G protein coupled receptor" would not constitute an adequate search of the claimed subject matter because there is a multitude of G protein coupled receptors in the art. As stated in the office action mailed on 5/12/2005, the groups are drawn to methods involving different modes of operation or different effects, as well as different structural components. Additionally, the claims are drawn to compounds and methods related as product and product of use. Each of the groups would require a separate and distinct search based on the specific structural elements and/or method steps of each group. Additionally, although each of the groups are classified in the same class and subclass, this class and subclass are large, encompassing a multitude of inventions that would each require a separate search and examination. Classification into the same class and subclass does not mean that any invention within that class and subclass would necessarily return art against another

invention. Regardless of applicant's search of class 514, subclass 44, the examiner must perform a separate and independent search for each of the inventions and a search burden remains.

The requirement for restriction is still deemed proper and is therefore made FINAL.

Claims 2, 4, 6-13, 15-18, 20-24, 26, 27, 29, 31, 32 and 34-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/9/2005.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because there are sequences in figure 4 that do not contain a SEQ ID NO.

A complete response to this office action must correct the defects cited above regarding compliance with the sequence rules and a response to the action on the merits which follows.

The aforementioned instance of failure to comply is not intended as an exhaustive list of all such potential failures to comply in the instant application. Applicants are encouraged to thoroughly review the application to ensure that the entire

application is in full compliance with all sequence rules. This requirement will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5, 14, 19, 25, 28, 30 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what the metes and bounds of "mammalian sequence #115" are. Applicant has identified mammalian sequence #115 as both polynucleotide and polypeptide sequences. Specifically, SEQ ID NOs: 1, 3 and 5 are each disclosed as a cDNA sequence encoding mammalian sequence #115, whereas SEQ ID NOs: 2, 4 and 6 are each disclosed as predicted amino acid sequences of mammalian sequence #115. Therefore, it cannot be determined whether a polynucleotide or a polypeptide sequence is being instantly claimed, as both are identified as "mammalian sequence #115".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5, 14, 19, 25, 28, 30 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s)

contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The invention of the above claims is drawn to a method for identifying compounds useful for modulating body weight, the method comprising contacting a test compound with a mammalian sequence #115 and determining whether the test compound binds to the mammalian sequence #115. The invention is further drawn to a method of preparing a pharmaceutical composition comprising the test compound that binds to mammalian sequence #115 and a pharmaceutically acceptable carrier.

The claims encompass a method comprising contacting a test compound with any mammalian sequence #115. The standard terminology for referring to a particular sequence is by SEQ ID NO (see MPEP 2400). In the instant case, it appears that applicant intends for "mammalian sequence #115" to refer to a genus of sequences. It is unclear what is meant by "mammalian sequence #115", as this does not appear to be an art-accepted term. The instant sequence listing discloses murine, rat, and human sequences, each referred to as "mammalian sequence #115". One of ordinary skill in the art would not be able to practice the instantly claimed invention without knowledge of a specific sequence. Given the breadth of sequences embraced in the instantly claimed genus, one could not envision the member oligonucleotides of such a broad genus. Due to the lack of clarity with regards to the terminology "mammalian sequence #115", the skilled artisan would not be able to recognize that the applicant was in possession of the claimed genus at the time of filing.

Claims 1, 3, 5, 14, 19, 25, 28, 30 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention of the above claims is drawn to a method for identifying compounds useful for modulating body weight, the method comprising contacting a test compound with a mammalian sequence #115 and determining whether the test compound binds to the mammalian sequence #115, therefore identifying a compound useful for modulating body weight. The invention is further drawn to a method of preparing a pharmaceutical composition comprising the test compound that binds to mammalian sequence #115 and a pharmaceutically acceptable carrier. Although the claims are drawn to a method for identifying a compound useful for modulating body weight, the instant specification does not teach a link between a compounds ability to bind to mammalian sequence #115 and the modulation of body weight, except for by prophetic examples. Additionally, the art is silent as to the use of this specific GPCR (instantly claimed mammalian sequence #115) with regards to the modulation of body weight. Glucksmann et al. is considered to be the closest prior art and does not teach a correlation between the instantly claimed GPCR and modulation of body weight, nor has any teaching from the prior art been located that describes any such link between the instant mammalian sequence #115 and modulation of body weight. Additionally, the

method of preparing a pharmaceutical composition of instant claim 19 implies that the composition has a therapeutic or treatment benefit that is not enabled.

Due to the lack of guidance in the specification as filed, as well as in the prior art, regarding how identifying a test compound that binds to mammalian sequence #115 would impact modulation of body weight, there is no perceived correlation between binding to mammalian sequence #115 and modulation of body weight. If applicant is aware of such evidence, applicant is encouraged to provide it in the form of a declaration or by any other means so that such evidence may be considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 5, 14, 19, 25, 28, 30 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Glucksmann et al. (WO 99/37679).

The invention of the above claims is drawn to a method for identifying compounds comprising contacting a test compound with a mammalian sequence #115 and determining whether the test compound binds to the mammalian sequence #115, wherein the mammalian sequences #115 is expressed on the surface of a recombinant cell, wherein the recombinant cell is a eukaryotic cell, wherein the mammal is a mouse or a human. The invention is further drawn to preparing a pharmaceutical composition comprising a test compound predetermined to bind to a mammalian sequence #115 and a pharmaceutically acceptable carrier.

Glucksmann et al. teach the identification of a G-protein coupled receptor (GPCR) and nucleic acid molecules that encode the GPCR, referred to as the flh2882 protein and the *flh2882* gene, respectively. Glucksmann et al. teach methods of identifying compounds that bind and modulate the expression of the *flh2882* gene comprising contacting a cell with a candidate compound and determining the expression of the *flh2882* mRNA or protein (see page 32). The candidate compound is therefore identified as a modulator of *flh2882* nucleic acid expression. Glucksmann et al. specifically teach a 1728 nucleotide sequence, wherein nucleotides 1-1011 are 99.7% identical to a "mammalian sequence #115" (see instant SEQ ID NO: 5). This sequence is considered to be within the genus of polynucleotides instantly claimed, as the sequence comprises a sequence 99.7% identical to instant SEQ ID NO: 5, and both are disclosed to be G-protein coupled receptor sequences. Applicant has not claimed "mammalian sequence #115" by sequence, but rather by name. The sequence taught by Glucksmann et al. is considered to have the same function, as it comprises a portion

that is 99.7% identical to instant SEQ ID NO: 5. Additionally, the human and mouse "mammalian sequence #115" are disclosed as being extremely similar (see instant figure 4). Therefore, the sequence taught by Glucksmann et al. is considered to be substantially similar to the mouse sequence as well. Glucksmann et al. teach expression of the sequence in recombinant mammalian cells, and further teach a mouse and human gene sequence. Glucksmann et al. teach a method of preparing a pharmaceutical composition comprising a test compound determined to modulate the GPCR and a pharmaceutical acceptable carrier (see page 42). Therefore, the instant invention is anticipated by Glucksmann et al.

Claims 1, 3, 5, 14, 19, 25, 28, 30 and 33 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Liaw et al. (WO 02/068600 A2).

The invention of the above claims is drawn to a method for identifying compounds comprising contacting a test compound with a mammalian sequence #115 and determining whether the test compound binds to the mammalian sequence #115, wherein the mammalian sequences #115 is expressed on the surface of a recombinant cell, wherein the recombinant cell is a eukaryotic cell, wherein the mammal is a mouse or a human. The invention is further drawn to preparing a pharmaceutical composition comprising a test compound predetermined to bind to a mammalian sequence #115 and a pharmaceutically acceptable carrier.

Liaw et al. teach a G-protein coupled receptor (GPCR) and nucleic acid molecules that encode the GPCR. Liaw et al. teach methods of identifying compounds

that bind and modulate the expression of the GPCR comprising contacting a cell with a candidate compound and determining the expression of the GPCR. Liaw et al. teach the screening of candidate agonist and antagonist compounds. The candidate compound is therefore identified as a modulator of a GPCR. Liaw et al. specifically teach a human GPCR sequence 1014 nt in length (SEQ ID NO: 97 of Liaw et al.) that is 98.3% identical to a "mammalian sequence #115" (see instant SEQ ID NO: 5). This sequence is considered to be within the genus of polynucleotides instantly claimed, as the sequence is 98.3% identical to instant SEQ ID NO: 5, and both are disclosed to be G-protein coupled receptor sequences. Applicant has not claimed "mammalian sequence #115" by sequence, but rather by name. The sequence taught by Liaw et al. is considered to have the same function, as it is 98.3% identical to instant SEQ ID NO: 5. Additionally, the human and mouse "mammalian sequence #115" are disclosed as being extremely similar (see instant figure 4). Therefore, the sequence taught by Liaw et al. is considered to be substantially similar to the mouse sequence as well. Liaw et al. teach expression of the sequence in recombinant mammalian cells, and further teach the usage of mouse and human cells. Liaw et al. teach a method of preparing a pharmaceutical composition comprising a test compound determined to modulate the GPCR and a pharmaceutical acceptable carrier (see page 30). Therefore, the instant invention is anticipated by Liaw et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is 571-272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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